510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR Part 807.92.

The assigned 510(k) number is: K073039

1. Date of Summary: October 18, 2007

2. Submitted by: Princeton BioMeditech Corporation
4242 U.S. Route 1, Monmouth Jct., NJ 08852
Phone: 732-274-1000
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JAN 24 2008

3. Device Name: Trade Names: SpermCheck® Vasectomy
Common or Usual Name: Semen analysis test device
Classification Name: Obstetrics/gynecology

4. Identification of legally marketed devices to which claims of equivalence are made:
Hemacytometer
K041039, Fertell Male Fertility Test by Genosis Ltd.
K011679, FertilMARQ™ Home Diagnostic Screening Test for Male Infertility, by Embryotech Laboratories, Inc.

5. Device Description: SpermCheck® Vasectomy is an immunochromatographic test for the rapid, qualitative detection of sperm concentration.

6. Intended Use: SpermCheck® Vasectomy is a rapid qualitative test that detects low concentrations of sperm at or above 250,000 sperm/mL in human semen as an aid for vasectomized men. For *in vitro* OTC home use.

7. Substantial Equivalence: SpermCheck® Vasectomy is substantially equivalent to standard microscopic analysis (counting by Hemacytometer) based on WHO guidelines in its performance and K041039, Fertell Male Fertility Test manufactured by Genosis Ltd in the principle of the test. Both Fertell Male Fertility and SpermCheck® Vasectomy tests are Chromatographic Immunoassays to detect sperm concentration qualitatively. FertilMARQ™ Home Diagnostic Screening Test for Male Infertility, K011679, is also substantially equivalent in detecting sperm concentration qualitatively by color.

Conclusion: SpermCheck® Vasectomy is substantially equivalent to standard microscopic analysis (counting by Hemacytometer), K041039; Fertell Male Fertility Test manufactured by Genosis Ltd., and K011679, FertilMARQ™ Home Diagnostic Screening Test for Male Infertility manufactured by Embryotech Laboratories, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Princeton BioMeditech Corporation
c/o Dr. Kyung-ah Kim
Director
4242 US Route 1
Monmouth Junction, NJ 08852

JUN 15 2012

Re: k073039
Trade/Device Name: SpermCheck® Vasectomy
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Date: October 18, 2007
Received: October 29, 2007

Dear Dr. Kim:

This letter corrects our substantially equivalent letter of January 24, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073039

Device Name: SpermCheck® Vasectomy

Indications For Use:

SpermCheck® Vasectomy is a rapid qualitative test that detects low concentrations of sperm at or above 250,000 sperm/mL in human semen as an aid for vasectomized men.
For *in vitro*, over the counter home use.

Prescription Use _____ AND/OR Over-The-Counter Use ___√___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Page 1 of 1

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K073039